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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/360,934 07/26/99 COVACCI

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027476 HM12/0913  
CHIRON CORPORATION  
INTELLECTUAL PROPERTY - R440  
P.O. BOX 8097  
EMERYVILLE CA 94662-8097

EXAMINER

BUI, P

ART UNIT

PAPER NUMBER

1638

DATE MAILED:

09/13/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/360,934

Applicant(s)  
Covacci et al.

Examiner  
Phuong Bui

Art Unit  
1638



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 6, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 38-40 and 42 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- 5) ☒ Claim(s) 40 is/are allowed.
- 6) ☒ Claim(s) 38, 39, and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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### **DETAILED ACTION**

1. The Office acknowledges the receipt of applicant's after-final amendment E, Paper No. 22 filed August 6, 2001. The amendment of August 6, 2001 has been entered. In view of the new written description guidelines and upon further consideration, the finality of the previous Office action has been vacated in favor of the rejections set forth below. Any inconvenience to Applicant is deeply regretted. Claims 38-40 and 42 are pending and are examined in the instant Office action.

#### ***35 U.S.C. 112, second paragraph***

2. For further clarification, "substantially no toxicity" and "substantially reduced toxicity" in the claims is understood by the Office to mean "does not exhibit statistically significant cytotoxic effects to a *H. pylori* host" (p. 8 of Amendment of August 7, 2000), and cytotoxic effects being defined as having the ability to cause vacuolation and cell death (p. 5, specification).

#### ***35 U.S.C. 112, first paragraph***

3. Claims 38, 39 and 42 are rejected 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *H. pylori* cytotoxin SEQ ID NO:3 and immunogenic fragments thereof, does not reasonably provide enablement for any polypeptide having substantially no toxicity. The specification defines cytotoxin of *H. pylori* as the protein, and fragments thereof, whose nucleotide sequence and amino acid sequence are shown in Figs. 1 and 2, respectively, and their derivatives, and whose molecular weight is about 140 kDa (p. 5). The specification also defines polypeptide as having an amino acid sequence identical to that of a

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polypeptide encoded in the sequence, or a portion thereof wherein the portion consists of at least 3-5 amino acids (p. 14). Based upon these definitions, the claimed polypeptide can be any 3-5 amino acids from any source, since it is unclear what properties are retained in the derivatives. Applicant should also note that the claimed polypeptide is “recombinantly produced” and does not require that the claimed polypeptide be isolated/purified from *H. pylori* cytotoxin. However, Applicant has not enabled a use for any 3-5 amino acid polypeptide from any protein and any source, since such a polypeptide cannot be used in diagnosis of *H. pylori* or to elicit an immune response specific to *H. pylori*, or for any other uses specific to *H. pylori* or its cytotoxin. Similarly, claims 40 and 43, which comprise at least ten or fifteen amino acids, respectively, are also not enabled since no SEQ ID NO. was cited and thus the claims read on any 10 or 15 amino acids from any source.

Assuming *arguendo* that the claims do not read on any protein from any source, but that the 3-5 amino acids are obtained from *H. pylori* cytotoxin, Claim 38 is still not enabled because it does not require inducing of the production of antibodies specific to *H. pylori*. The specification discloses diagnostic and vaccine applications (p. 4). Vaccine applications are not enabled for reasons of record. Diagnostic applications minimally require antigen-antibody interaction, which claim 38 does not require. It is unclear how one skilled in the art would be able to use a 3-5 amino acid sequence which is not specific to *H. pylori* cytotoxin and does not induce production of antibodies to *H. pylori* for diagnostic purposes or any other well-established uses without undue experimentation. For example, the attached oligopeptide sequence search

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results disclose proteins having an eight consecutive amino acid match with various regions of Applicant's SEQ ID NO:3 which are not *H. pylori* cytotoxins. Thus, antibodies produced to any of these eight polypeptides would not be specific to *H. pylori*. Accordingly, Applicant has not enabled 3-5 amino acid polypeptides which do not induce the production of antibodies specific to *H. pylori* for any disclosed or well-established applications as commensurate in scope with the claims.

4. Claims 38, 39 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. Aside from the fact the claims broadly read on a protein of any size from any source, which Applicant is clearly not in possession of, the breadth of the claims also encompasses all *H. pylori* cytotoxin mutants and allelic variants. Applicant discloses the cytotoxin sequence from *H. pylori* strain CCUG 17874 (p. 48). There is insufficient relevant identifying characteristics from a single strain to allow one skilled in the art to predictably determine complete structures of other cytotoxin sequences from other *H. pylori* strains, or their mutants and allelic variants, absent further guidance. Since the claimed genus, i.e, CT (cytotoxin) polypeptides, encompasses undisclosed CT polypeptides from other species (strains) yet to be discovered, the disclosed structural feature for one species (strain) does not constitute a substantial portion of the claimed genus. Therefore, the disclosure of a single cytotoxin sequence from a single strain of *H. pylori* does not provide an adequate

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description of the claimed genus, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the genus of CT polypeptides as claimed (see Written Description Requirement published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111). It is suggested that Applicant recite SEQ ID NO:3 in the claims to obviate this rejection.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 38, 39 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Joab et al. (J. Virol., Oct. 1987, Vol. 61, No. 10, p. 3340-3344 (U)), Murakami et al. (DNA, 1987, Vol. 6, No. 3, p. 189-197 (V)), Rettenmier et al. (J. Clin. Invest., 1986, Vol. 77, No. 6, p. 1740-1746 (W)), Trevino et al. (Infect. and Immun., Jul 1986, Vol. 53, No. 1, p. 129-134 (X)), Sibold et al. (Biochimie, 1984, Vol. 66, p. 547-556 (Y)), or Stunnenberg et al. (Nucleic Acids Research, 1988, Vol. 16, No. 6, p. 2431-2444 (Z)). Based upon Applicant's disclosure, the claims read on any polypeptide from any source (see 112 1st rejection above). The "recombinant" limitation does not require the polypeptide be isolated and purified from *H. pylori*. Each of the references teaches a recombinant protein having a molecular weight of about 140 kDa. None of the proteins

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of the prior art has cytotoxic effects causing vacuolation and cell death to a *H. pylori* host cell.

Accordingly, the cited prior art anticipated the claimed invention.

7. Claim 40 is allowable.

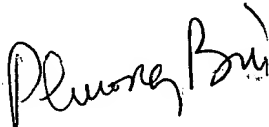
8. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996. The Examiner can normally be reached Monday-Friday from 6:30 AM - 4:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui  
Patent Examiner  
Group Art Unit 1638  
August 31, 2001

  
PHUONG T. BUI  
PRIMARY EXAMINER